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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,996	11/21/2003	Ning Wei	KCX-742 (19795)	9086
22827	7590	07/11/2007		
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER DIRAMIO, JACQUELINE A	
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			07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/718,996	Applicant(s) WEI, NING	
	Examiner Jacqueline DiRamio	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12, 13 and 15-36 is/are pending in the application.
- 4a) Of the above claim(s) 15-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/11/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Applicant's amendments to claim 1 and cancellation of claims 10, 11, and 14 are acknowledged.

Currently, claims 1 – 9, 12 and 13 are pending and under examination. Claims 15 – 36 are acknowledged as withdrawn as drawn to a non-elected invention.

Withdrawn Objections and Rejections

The previous objection to claim 1 is withdrawn in view of Applicant's amendments filed April 24, 2007.

The previous rejection of claims 1 – 14 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendments filed April 24, 2007.

All previous rejections of the claims under 35 U.S.C. 102 and 103 are withdrawn in view of Applicant's amendments and arguments filed April 24, 2007.

Response to Arguments

Applicant's arguments, see p5, filed April 24, 2007, with respect to the rejection(s) of the claim(s) under 35 U.S.C. 102(b) and 103(a) have been fully considered and are persuasive. Applicant's amendments to claim 1 requiring calibration probes and a calibration zone containing a capture reagent for said detection probes or said calibration probes, wherein the intensity of the detection signal is compared to the intensity of the calibration signal created in the calibration zone, are not taught by the

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previously applied references of Buck (US 6,258,548), Manita (US 6,177,281), or Harris et al. (US 2003/0162236). Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and presented below.

NEW GROUNDS OF REJECTION

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1, line 13, contains the term "and" at the end of method step iii), which appears incorrect because there are additional steps after the method step iv).

Claim 1 fails to include the term "and" after the method step v) and prior to the final method step vi).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 9, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks et al. (US 6,509,196) in view of Buck (US 6,258,548).

Brooks et al. teach a method for detecting an analyte in a test sample, said method comprising:

i) providing a flow-through assay device comprising a porous membrane that is in fluid communication with test particles (detection probes) and internal control particles (calibration probes), one or more of said test particles being conjugated with a binding agent (specific binding member) for the analyte, wherein the assay device defines a detection zone containing a detection reagent (capture reagent) for the analyte and a control reaction zone (calibration zone) containing a control detection reagent (capture reagent) for said internal control particles;

ii) contacting said conjugated test particles with the test sample;

iii) allowing the test sample and said conjugated test particles to flow to said detection zone so that said conjugated test particles or complexes thereof bind to said detection reagent and generate a detection signal;

iv) allowing said test particles and internal control particles to flow to said control reaction zone so that said internal control particles bind to said control detection reagent and generate a control signal; and

v) comparing the intensity of the detection signal to the intensity of the control signal, the quantity of the analyte within the test sample being proportional to the

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intensity of the detection signal calibrated by the intensity of the control signal (see column 1, lines 28-67; column 2, lines 1-30; column 3, lines 43-63; column 4, lines 16-50; column 5, lines 1-67; column 6, lines 1-67; column 7, lines 1-67; column 8, lines 1-31; column 9, lines 43-67; and column 10, lines 1-10).

However, Brooks et al. fail to teach the inclusion of a scavenging zone with the assay device, the scavenging zone containing a capture reagent for the analyte, wherein the test sample is contacted with the scavenging zone so that a quantity of the analyte less than or equal to a predefined base quantity binds to said capture reagent in the scavenging zone prior to the contacting of the test sample with the detection probes or detection zone.

Buck teaches a lateral flow test strip and method for detecting an analyte in a test sample utilizing the test strip, wherein the method comprises:

i) providing the lateral flow test strip (flow-through assay device) comprising a porous membrane that is in fluid communication with an indicator reagent (detection probes) conjugated with a specific binding ligand (member) for the analyte, wherein the test strip defines an analyte modulating zone (AMZ) (scavenging zone) and an analyte test zone (ATZ) (detection zone), each of said zones containing an immobilized binding ligand (capture reagent) for the analyte;

ii) contacting said AMZ with the test sample so that a quantity of the analyte equal to a predefined base quantity binds to said immobilized binding ligand at said AMZ;

iii) contacting said conjugated indicator reagents with the test sample; and

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iv) allowing the test sample and said conjugated indicator reagents to flow to said ATZ so that said conjugated indicator reagents or complexes thereof bind to said immobilized binding ligand and generate a test (detection) signal. The analyte modulating zone (AMZ) is included with the test strip in order to remove a fraction of the analyte from the sample prior to the sample reaching the analyte test zone (ATZ) to thereby increase the detectable range of analyte concentration, which is beneficial for samples that contain a high concentration of analyte (see Figure 1; column 2, lines 35-60; column 3, lines 30-67; column 4, lines 1-67; column 5, lines 17-34; Example 1 and Table 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the method of Brooks et al. a scavenging zone or analyte modulating zone (AMZ), wherein the sample is contacted with the AMZ prior to reaching the detection or test zone, as taught by Buck because Buck teaches the benefit of including an analyte modulating zone (AMZ) with a test strip in order to remove a fraction of an analyte from a test sample prior to the sample reaching an analyte test zone to thereby increase the detectable range of analyte concentration, which is beneficial for samples that contain a high concentration of analyte.

With respect to Applicant's claims 2, 3 and 6, Buck teaches that the immobilized binding ligand at both said AMZ and said ATZ comprises a capture antibody (see column 2, lines 35-52; column 4, lines 36-38; column 5, lines 17-34; and Example 1).

With respect to Applicant's claims 4 and 5, Brooks et al. teach that the analyte can comprise an antigen and the detection reagent in the detection zone can comprise an antibody, antigen, or hapten (see column 4, lines 16-41; column 6, lines 41-46; and column 7, lines 8-16).

With respect to Applicant's claim 7, Buck teaches that the test sample contacts the conjugated indicator reagents only after contacting said AMZ (see Figure 1; column 5, lines 17-34; and Example 1).

With respect to Applicant's claim 8, Buck teaches that the test strip comprises a wicking pad 14 (sampling pad) that defines said AMZ (see Figure 1; and column 5, lines 17-34).

With respect to Applicant's claim 9, Buck teaches that the test strip includes a reagent pad or conjugate pad 18 located downstream from said wicking pad 14, wherein said conjugated indicator reagents are applied to said reagent pad (see Figure 1; column 3, lines 46-60; column 5, lines 17-34; and Example 1).

With respect to Applicant's claim 12, Brooks et al. teach that the test particles comprise a substance, such as liposomes, luminescent labels, fluorescent labels, phosphorescent particles, or latex particles (direct visual labels) (see column 5, lines 15-40).

With respect to Applicant's claim 13, Buck teaches that the binding ligand (capture reagent) or capture antibody is immobilized in said AMZ (see column 5, lines 17-34 and Example 1).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

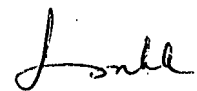
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jackie DiRamio
Patent Examiner
Art Unit 1641


LONG V. LE 07/02/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600